

Complication Rate of Laparoscopic Hysterectomies in Denmark, 2011–2016

Olav Istre, MD, PhD, Dorthe Snebjerg, MD

ABSTRACT

Background and Objectives: After the U. S. Food and Drug Administration's recommendation against the use of power morcellation for tissue extraction in minimally invasive hysterectomy, the number of procedures completed laparoscopically declined in favor of open surgery laparotomy. We conducted a retrospective cohort study comparing perioperative and long-term outcomes, including complications associated with laparoscopic hysterectomy before and after the FDA recommendation.

Methods: We included procedures performed in Danish government hospitals (GHs) and a hospital specializing in minimally invasive gynecological surgery (MIGS). Different types of hysterectomy over the period from January 2011 through May 2016 were examined.

Results: Hysterectomies were analyzed from GHs ($n = 21,495$) and from a hospital specializing in MIGS ($n = 749$). In the GHs, we found a decrease in open hysterectomy from 40% in 2011 to 20% in 2016. In the MIGS hospital, 4 of 749 (0.05%) open hysterectomies were performed during the 6 years; however, there was a change in operative technique. After the FDA recommendation, there was a shift from laparoscopic subtotal hysterectomy (LSH) to total laparoscopic hysterectomy (TLH) from 32% in 2011 to 82% by May 2016. Containment bags were used in LSH and large-uterus TLH after the 2014 advisory. Significantly more complications occurred in the GHs than in the MIGS hospital: 3224/21,495 (15%) vs 53/749 (7.0%), respectively.

Conclusion: The rate of minimally invasive hysterectomies continues to increase. However, after 2014, many of the morcellation techniques have been replaced by a

minilaparotomy to extract the uterus at the end of surgery, compared to the use of the contained morcellation in 100% of cases in the MIGS hospital. There was a major difference in complication rates between the hospitals that is partly explainable by the challenge in training residents and the low operative volume of surgeons in GHs.

Key Words: Laparoscopic subtotal hysterectomy, Power morcellation, Total abdominal hysterectomy, Total laparoscopic hysterectomy, Hysterectomy complications.

INTRODUCTION

Minimally invasive gynecologic surgery (MIGS) has expanded significantly over the past years, and hysterectomy remains the most common major gynecologic surgery performed. There has been a gradual shift away from abdominal hysterectomy in favor of minimally invasive techniques.¹

Methods available for hysterectomy are total abdominal hysterectomy (TAH), vaginal hysterectomy (VH), laparoscopic hysterectomy (LH), laparoscopic subtotal hysterectomy (LSH) and robotic-assisted hysterectomy (RAH). The benefits of minimally invasive approaches over TAH, including faster recovery time, less blood loss, fewer infections, and shorter hospital stay,² have caused more and more women to seek laparoscopic hysterectomy.

The laparoscopic power morcellator was introduced in the 1990s. This tool made it possible to remove large fibroids during myomectomy or hysterectomy and still use a laparoscopic technique. Power morcellation allowed previously ineligible women to undergo minimally invasive gynecologic surgery.³ These devices have provided a method for removing large uteri and fibroids from the peritoneal cavity without the need for a laparotomy incision. Despite the known benefits of power morcellation devices for most patients, on November 24, 2014, the Food and Drug Administration (FDA) issued the following warning to health care providers: Laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or postmenopausal, or are candidates for en bloc

Department of Obstetrics and Gynecology South Danish University, Odense, Denmark, and Aleris Hamlet Private Hospital, Copenhagen, Denmark (Dr Istre).

Aleris Hamlet Private Hospital, Copenhagen, Denmark (Dr Snebjerg).

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Address correspondence to: Olav Istre, MD, PhD, Aleris Hamlet Private Hospital, Copenhagen, Denmark, Phone +4521277472. E-mail: oistre@gmail.com

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tissue removal—for example, through the vagina or a minilaparotomy.⁴ In rare cases, the tissue reveals the presence of sarcoma, and the malignant cells, spread inadvertently during morcellation, may lead to upstaging of the cancer and worsen the prognosis of the patient.⁵ In Denmark, the National Board did not issue a warning; however, it was stressed that patients should be informed of the concerns about morcellation, and, as a result, the use of power morcellation ceased almost completely, and containments bag were rarely used.

There has been a concern about a decrease in minimally invasive hysterectomies, and these concerns have been confirmed by a 5.8% decrease in minimally invasive hysterectomies and a 19% decrease in myomectomies in a U.S. study from Florida.¹

We evaluated hysterectomy trends in Denmark, to identify whether there has been a change in surgical practice and complication rates, as well as secondary outcomes immediately after the FDA warning statement discouraging the use of uncontained power morcellation in the surgical treatment of uterine fibroids. We have looked at and compared 2 hospital settings: government hospitals (GHs) that perform fewer MIGS procedures and a dedicated MIGS hospital.

METHODS

The present study was a retrospective cohort study and analysis of the national case log reports from the Danish Hysterectomy Database, which includes all types of hysterectomies performed in Denmark and all types of complications. In Denmark, every resident is, at the time of birth or immigration, assigned a unique and permanent civil registration number that enables linkage between nationwide administrative registers on the individual level. All information about diagnoses and procedures is recorded in the National Patient Register (NPR), an administrative register covering all hospital, including private hospitals, in Denmark.⁶ Each admission is registered at discharge with one primary and, if appropriate, one or more secondary diagnoses, according to the International Classification of Diseases, 10th revision (ICD-10). Accordingly each time a patient who has had a hysterectomy is readmitted to any Danish (including private) hospital or has a follow-up visit in an outpatient clinic, a record is made in this database. These data are free and publicly available on the Danish hysterectomy website (www.dsog.dk). We reviewed the data from January 2011 through May 2016; a 5.5-year period. We compared the numbers and the trends, to identify whether the FDA

recommendation had any influence on the way hysterectomies have been performed at GHs and our MIGS hospital. We also collected data on surgical complications at GHs, which have the responsibility to teach and train residents and fellows, compared to a single large unit specialized in MIGS, which trains fellows, but to a lesser extent than do the GHs. The patients' records from the MIGS hospital were collected and analyzed.

The morcellating technique changed from 2014 to a contained approach, which includes a bag with a sleeve for the optic (Espiner Medical, Clevedon, UK). The bag was inserted through the umbilical incision, the uterus placed in the bag, and the bag insufflated to 15 mm Hg, creating a lining in the abdominal cavity. The uterus is then morcellated, using a power morcellator of 15 or 20 mm (Wolf, Hamburg, Germany) through the umbilical incision and the camera through the trocar in the right iliac fossa, which holds the sleeve.

The complications were classified as (1) repeat surgery; (2) infection rupture of vault sepsis; (3) organ lesions; and (4) perioperative bleeding. To gather data on complications equally in both types of unit, all results from patient records were evaluated from the NPR register. The primary surgeon in the MIGS hospital has 15 years of experience in MIGS and has performed more than 1000 laparoscopic hysterectomies. The primary objective was to evaluate the change in technique over the years and if the FDA's morcellation warning had any influence. The secondary objective was the difference in clinical practice and complications between the 2 types of hospital.

Statistics

A 2-tailed *t* test was used to calculate the *P*-values for changes in the number of each type of hysterectomy and complications from January 2011 through May 2016 and the mean number of hysterectomies and the change in operative technique during the study period. One-way ANOVA was used to show significantly different operation type and details from each year before and after introduction of the containment bag for morcellated tissue in 2014. Significance level < 0.05. The software used was SPSS (IBM, Chicago Illinois, USA).

RESULTS

In Denmark with a population of 6 million, an average of 4500 benign hysterectomies are performed annually. During the period from January 2011 through May 2016, a total of 21,495 hysterectomies were performed. An in-

crease in minimally invasive hysterectomies (TLH, LSH, and VH) was seen, with a total increase from 60% to 80%; however, a slight decrease in VH (15% to 12%) was seen, as well as a shift to TLH (from 45% to 64%). Furthermore, total abdominal hysterectomy (TAH) has decreased from 40% in 2011 to 20% in 2016.

Nevertheless, since 2014, when the FDA recommendation was published, the amount of minimally invasive hysterectomies continued to increase, although the LSH (which includes morcellation) has decreased from 5% to 3%.

In **Table 1**, the hysterectomy data for all the procedures at the MIGS hospital (n = 749) are listed for operating time (mean, 77 min), BMI (mean, 25) , intraoperative bleeding

(mean, 72 mL) and weight of the uterus (mean, 322 g) during the same time frame.

Since 2014, the hysterectomies with large fibroids (uterus >500 g) have been removed with a contained morcellation technique at the MIGS hospital. In cases with a smaller uterus that could be extracted en bloc, through the vagina, patients underwent a TLH instead of an LSH, and this change prompted a shift from LSH to TLH (from 32% in 2011 to 82% in 2016) (**Figure 1**). Operative time increased significantly in the contained morcellation cases with a specimen weight >500 g after 2014; the mandatory use of the bag increased the time by 15 minutes, compared to times in previous years with the same size specimen (**Figure 2**). The mean maximum size specimen

Table 1.
Consecutive Hysterectomies: MIGS Hospital

		Operative Time (min)	BMI	Blood Loss (mL)	Uterus Weight (g)
LSH	Mean	80.47	24.46	86.11	437.01
	n	265	265	265	265
	SD	26.987	3.946	121.137	327.636
	Minimum	35	18	5	50
	Maximum	240	42	900	1750
TLH	Mean	73.89	25.21	54.37	272.85
	n	406	406	406	406
	SD	25.551	4.384	71.430	210.019
	Minimum	28	16	5	20
	Maximum	180	44	550	1265
Vaginal	Mean	81.12	24.59	59.46	74.33
	n	74	74	74	73
	SD	24.579	3.682	57.550	52.325
	Minimum	40	17	0	20
	Maximum	150	38	300	253
TAH	Mean	142.50	30.25	117.500	2128.75
	n	4	4	4	4
	SD	45.000	10.658	736.546	1089.253
	Minimum	90	20	300	850
	Maximum	180	44	2000	3400
Total	Mean	77.30	24.91	72.09	321.56
	n	749	749	749	748
	SD	26.677	4.238	131.154	310.418
	Minimum	28	16	0	20
	Maximum	240	44	2000	3400

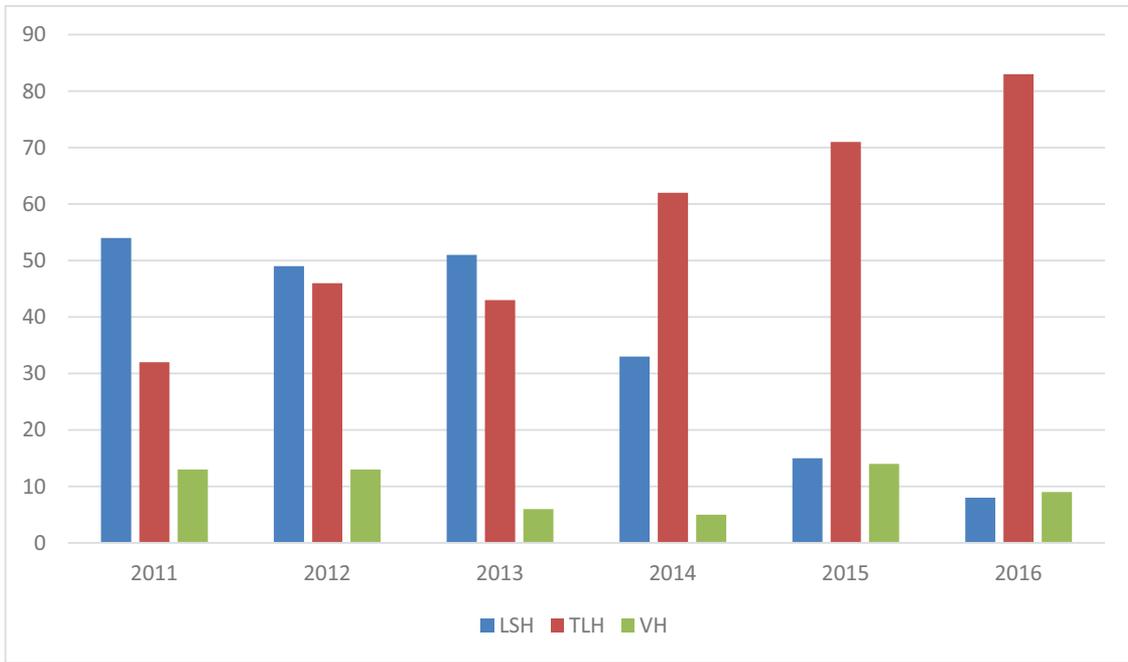
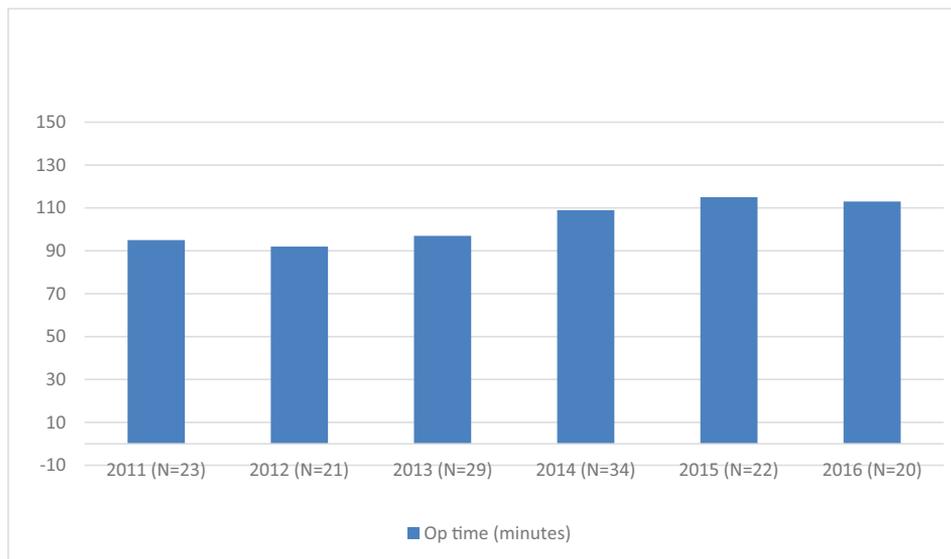


Figure 1. Laparoscopic hysterectomy methods over the years at the MIGS hospital.



Year	2011	2012	2013	2014	2015	2016	
Op Time	95	93	97	109	115	113	P=0,024
Specimen Weight	706	859	844	763	720	910	P=0,376

Figure 2. Hysterectomies from 2011 through May 2016 with specimens weighing >500 g. From 2014, procedures included power morcellation. P values (anova) 2011 vs 2016.

morcellated at the MIGS during the LSH and TLH procedures was 1750 and 1265 g, respectively. The hysterectomy specimen weight exceeding 500 g was 16% in GHs compared to 20% in the MIGS hospital setting. Four TAHs with a mean specimen size of 2128 g (3400–2000 g, maximum–minimum) were performed in the MIGS hospital during the 6-year study (Table 1).

The histology (in the MIGS hospital) revealed fibroids in 465 of 749 (62%) cases (Table 2) and 2 cases of uterine sarcoma: 1 in the VH group and 1 in the TLH group with contained morcellation.⁷ The patient in the TLH case underwent a positron emission tomographic scan 6 weeks after surgery that showed 4 lung metastases; however, none was seen below the diaphragm.

Complications

Complications after hysterectomies were seen in the NPR and Danish Hysterectomy Database, which also register all types of contact, admittance, surgery, and intervention data (Tables 3 and 4). The overall complication rate in the GH was 3223/21495 (15%); infection, rupture of vault, sepsis, 1612 (7.5%); repeat surgery, 795 (3.7%); perioperative bleeding complications, 494 (2.3%); and organ lesion, 322 (1.5%); compared with 53 (7.0%), 36 (4.8%), 2 (0.2%), 4 (0.5%), and 10 (1.4%), respectively, in the MIGS, a significant difference, $p < 0.05$ (Tables 3, 4).

DISCUSSION

The proportion of minimally invasive hysterectomies has increased in the past decade, with benefits for the patients, including shorter recovery time, improved cosmetics, and less postoperative pain.^{8,9}

An important question that we looked at is whether the FDA recommendation of morcellation has changed the practice and its influence on the procedures performed. In

Table 2.
Histology Specimens: MIGS Hospital

Conditions	Frequency	%
Endometriosis	57	7.6
Fibroids	465	62.0
Menorrhagia	65	8.5
Uterine prolapse	71	9.5
Dysplasia/malignant	4	0.5
Other	87	11.6
Total	749	

Table 3.
Complication Rate: Government Hospitals

Complication	Cases (n)	Portion of Total (%)	CI (95% Confidence interval)
Repeat surgery	795	3.7	2.6–4.2
Infection, rupture, sepsis	1612	7.5	5.5–8.1
Organ lesions	322	1.5	1.2–2.0
Perioperative bleeding >1000 mL	494	2.3	1.5–4.2
Total complications	3223	15	13–16

Number of hysterectomies examined: 21,495.

Table 4.
Hysterectomies: MIGS Hospital

Complication	Cases (n)	Portion of Cases (%)
Repeat surgery	2	0.2
Infections	36	4.8
Organ lesions: ureter, bladder, bowel	10	1.3 ± 0.1 (SD)
Perioperative bleeding >1000 mL	4	0.5
Complications	52	7.0 ± 0.257 (SD)

Number of hysterectomies examined: 749.

the GHs, there was a decrease over time in open hysterectomies. These results are in line with those in other studies, and we did not see any decrease in MIGS procedures¹⁰; however, there has been a change from morcellation to minilaparotomy in cases with the uterus exceeding >500 g,³ and they were still coded as MIGS procedures, which could be argued. The power morcellation technique almost disappeared in Danish hospitals after 2014 (personal communication from the Danish representative, Espiner Medical, Clevedon, UK). The reduction of 24% decrease in the supracervical approach to hysterectomy was also noted by Ottarsdottir et al.¹⁰ These result are in line with our findings of a marked change from supracervical to TLH (Figure 1).

In the MIGS hospital, we were recorded the operating time and the 15-minute increase in time (from 2013–2005) was in line with other studies.³ However, the use of a collection bag has had other benefits, such as protection of the bowel, as the intra-abdominal organs are compressed and protected, away from the morcellation area,

as well as the opportunity to collect all small specimens and blood, and of course avoiding contamination from unsuspected malignancies.^{7,10}

The shift from LSH to TLH is in line with other studies where the subtotal has decreased due to the morcellation discussion.¹¹ Presently, we usually do not offer LSH for the smaller uterus (<500 g) because it is faster and less complicated to extract the uterus vaginally. However if we want to maintain MIGS in the larger fibroid uteri, the ability to morcellate is mandatory. We believe that the technological evolution and advancement will eventually help to make using the technique easier.

Some public hospitals tried to perform morcellation in a bag, but experienced technical difficulties. In our unit, specializing in MIGS, we were able to perform almost all of the hysterectomies with laparoscopy.

Fibroid Size

A large uterus increases the technical challenge of hysterectomy, in any mode. It has thus been recommended that uterine size with specimen weight 500 g serves as the upper limit for the safe performance of a minimally invasive surgical method. As more surgeons have acquired the skills to perform technically advanced laparoscopic hysterectomy, the practice of using uterine size as a contraindication to laparoscopy has come into question.¹² In our MIGS hospital, 149 (20%) of the hysterectomies involved uteri >500 g during the 6-year period, and we perform of all them with the laparoscopic technique. Apart from 4 with the open technique, all of these cases involved specimens >2 kg. In the GH hospitals, 16% were >500 g compared to 20% in the MIGS hospital, indicating that it is possible to continue to perform laparoscopy for the benefit of the patients. The method used in laparoscopy with a large uterus is to place the trocars high, with the camera port usually 6 cm above the umbilicus.¹² Most of these hysterectomies were subtotal, with contained morcellation after 2014. Our experience demonstrates that it is possible to continue to perform MIGS techniques, even after the FDA warning. The fact that the size of the uterus is significantly higher in the MIGS unit indicates no selection bias of cases between the 2 units.

Sarcoma

Leiomyosarcoma (LMS) is a rare, malignant, aggressive tumor originating from smooth muscle tissue.¹³ Most LMS tumors arise de novo; malignant transformation is known, but very rare. Uterine LMS has been the subject of much discussion, because of cases in which a suspected benign

leiomyoma has been power morcellated, and subsequent pathology has shown it to be LMS. Some of these cases received public attention and compelled the FDA to issue a warning against uncontained power morcellation. This statement resulted in the ban of morcellation in many U.S. hospitals.

The rate of unsuspected LMS is estimated to be ~0.09%.¹³ The true prevalence is not known, but the incidence rate is estimated to be 0.4 per 100,000 in the Scandinavian countries.¹³ Four cases of mechanical open morcellation of occult leiomyosarcoma occurred in 2012–2013 in Denmark. Because of these cases, all Danish women with presumed benign leiomyomas should be informed about the possibility of malignant spread, a mandatory recommendation from the National Board of Health in 2014.¹⁴ However, the National Board did not comment on contained morcellation, even though one system (Pneumoliner; Olympus, Hamburg, Germany) has been approved by the FDA.^{7,15}

Complications

The complication rate was significantly higher in the GHs, and there are several explanations for the higher frequency. The learning curve for hysterectomy is ~75 cases.¹⁶ The GHs have the responsibility of training residents and fellows, and there are relatively few cases for each doctor; therefore, the top of the learning curve for TLH is reached much later,¹⁶ as confirmed by the decrease in operating time (accompanied by no change in complications) correlating with gain in practice. On the other hand, one should not forget that laparoscopy is not a complication-free procedure and that achievement of the top of the learning curve does not exclude the occurrence of complications. Very few doctors in the GHs will reach the required number of surgeries, but, in the MIGS hospital, the number is reached after 6 months. The increased blood loss in the GHs can be explained by the learning curve and technique, with most of the bleeding occurring when securing the uterine artery pedicles. In our experience, the surgeon should be aggressive in securing the pedicles carefully, coagulate both sides before cutting, and skeletonize the vessels and use sufficient bipolar energy, rather than blindly trusting ultrasound energy. Damage to other organs is also a technical problem, as is use of a uterine manipulator and deficiencies in knowledge of anatomy and experience. Several studies support these statements.^{9,16} In Denmark and many other countries, gynecology and obstetrics is a combined specialty, meaning that all residents go through training in surgical procedures, and it could be argued that doctors in training

should choose their subspecialty earlier, thus increasing the operative volume for the MIGS doctors.

CONCLUSIONS

Minimally invasive procedures are still performed at an increased rate in public hospitals in Denmark. However, since 2014, electronic power morcellation has been replaced with a mini laparotomy at the end of surgery, compared to almost 100% with no use of minilaparotomy in the MIGS unit. There is a major difference in incidence of complications between the units, and possible explanations are the training of residents and the low operative volume of doctors.

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